"Per Se Illegality for Reverse Payment Settlements?" Review of "Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality

Daniel A. Crane
University of Michigan Law School, dancrane@umich.edu

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PER SE ILLEGALITY FOR REVERSE PAYMENT PATENT SETTLEMENTS?

Daniel A. Crane[*]

Congratulations to Mike on a very fine book. I will confine my comments to Mike's chapter on patent settlements (Chapter 15), which I understand will also be coming out as an article in the *Michigan Law Review*.[1]

Patent settlements involving "reverse payments" are a huge topic on which I and many others have spilled much ink already.[2] Representative Bobby Rush (President Obama's erstwhile nemesis from Chicago's South Side) has just introduced legislation that would ban reverse payments.[3] I will not regurgitate my entire spiel on patent settlements here, but instead just try to highlight my essential disagreement with Mike and others who focus on reverse payment settlements between branded and generic pharmaceutical companies as a special antitrust problem.

Mike would make reverse payments—where the branded drug company pays the generic to leave the market—presumptively illegal. The settling parties would have a rebuttal right to demonstrate the reasonableness of the settlement in light of litigation costs, the generic's cash-strapped financial position, the parties' information asymmetries, and a catch-all reasonableness category. Mike contemplates, however, that courts might eventually find that these kinds of justifications were too weak, insubstantial, or infrequent to justify allowing a rebuttal case and simply make reverse payments per se illegal.

My basic problem with Mike's approach—and others that focus on reverse payment settlements as a unique species of antitrust problem—is that the social costs of anticompetitive patent settlements are only loosely correlated with the direction in which payment flows in the settlement. To repeat a claim that I've made on many occasions, the social cost of allow-

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* Professor of Law, University of Michigan.

1. Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37 (2009).

2. *See* Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747 (2002); Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698 (2004).

3. *See* Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009).

ing patent settlements that involve a cessation of competition between the branded and generic firm equals the social cost of the continuing branded monopoly (at least the deadweight loss, but include the wealth transfers if you like) times the probability that, but for the settlement, the generic would have won the patent infringement action and entered the market in competition with the branded firm.[4] There are also social costs to disallowing patent settlements, but let's put those aside for now.

What is the relationship between the social cost of cessation of competition between the branded and generic and the fact that the settlement payment flows from the branded to the generic? Nothing, unless the fact that the payment flows "abnormally" from the patentee-plaintiff to the infringer-defendant necessarily evidences that the plaintiff's claim is weak, which in turn means that the branded's probability of success in the infringement action is low and the social cost of the settlement is therefore high. However, as I've explained at length elsewhere, there are good reasons—particularly given the structure of the Hatch–Waxman Act[5]—why the payment flows in an "abnormal" direction even in a case in which there is a high probability that the patentee would have won the infringement action (and, consequently, the social cost of the settlement is relatively low).[6] In other words, the mere fact that a branded-generic settlement involves a "reverse payment" only weakly evidences the social cost of the settlement.

So antitrust rules that focus on "reverse payment" settlements as a category run the risk of creating false positives, but they also run the risk of creating false negatives to the extent that they focus the inquiry on the direction in which consideration flows—a not terribly helpful spot. It is often not hard to structure a branded-generic settlement in a way that does not involve reverse payments but still involves the key ingredients of social cost—the cessation of meaningful competition between the two firms and a low probability that a court would have enjoined the generic on patent infringement grounds. Scott Hemphill's empirical research on patent settlements following some of the early negative decisions (like the Sixth Circuit's *Cardizem* decision holding reverse payments per se illegal)[7] shows that creative lawyers are capable of crafting settlement agreements that have the same effects as the most pernicious reverse payment cases but would pass unscathed under a rule focusing on reverse payments.[8]

4. *See* Crane, *Exit Payments*, *supra* note 2, at 770–76.

5. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2006)).

6. *See* Crane, *Exit Payments*, *supra* note 2, at 770–76.

7. *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003).

8. C. Scott Hemphill, *Drug Patent Settlements Between Rivals: A Survey* (2007), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=969492.

Indeed, I have little doubt that if the Rush bill passes, antitrust lawyers will make a bundle of money restructuring patent settlement agreements to comply with the law. Here are some suggested reverse payment ban avoidance schemes:[9]

- Branded retains Generic to become its exclusive manufacturing and distribution agent for the branded's authorized generic. Utilizing its new-found freedom under *Leegin*,[10] Branded sets the resale price of the generic at an appropriate price-discriminatory discount off the branded price but nonetheless a monopoly price. Branded continues to collect monopoly rents by making generic pay an exorbitant royalty or annual lump-sum fee. If Generic can't afford the payments up front, Branded provides financing.
- Branded grants Generic an exclusive license to manufacture and distribute under the patent in Canada. Generic charges a monopoly price in Canada (so no one bothers re-importing), Branded charges a monopoly price in the U.S. There doesn't need to be any explicit agreement that Generic won't enter the U.S.—they get the point.
- The *Schering* scheme[11]—Generic licenses or sells Branded some worthless other drug for which Branded pays Generic some huge price. Investment bankers are paid to say the drug was worth it. Good luck litigating this as a reverse payment case—something like this worked in *Schering*.

I could go on, but the basic point is that the creativity of high-paid New York lawyers exceeds the foresight of anyone drafting legislation in this area. As much as I agree with Mike that patent settlements involving the cessation of competition between branded and generic firms are a big problem, the focus on reverse payments is off the mark.

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9. In the online version of this symposium, Mike rightly noted that Congressman Rush's bill would prohibit not merely cash reverse payments but also settlements where the ANDA filer "receives 'anything of value'" for discontinuing the manufacture of the drug. Posting of Administrator on behalf of Michael Carrier to Truth on the Market, http://www.truthonthemarket.com/ (Apr. 1, 2009, 11:57 EST), *available at* http://www.truthonthemarket.com/2009/04/01/professor-carriers-response/ (quoting H.R. 1706, 111th Cong. § 2 (2009). But in the first two examples of avoidance schemes I present here, the generic continues to manufacture the relevant drug but does so at monopoly prices because of royalty payment obligation. Those scenarios would not appear to be covered under the Rush bill. My basic point is that any rule focusing on the consideration paid to the ANDA filer—rather than on whether the patent infringement claim is strong or weak (which drives the social cost of allowing the settlement)—misses the boat.

10. Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877 (2007). During the online symposium, someone commented that *Leegin* applies only to vertical RPM, not to RPM between competitors. Certainly, a court might decide that a license agreement between competitors including a resale price maintenance provision exceeds the scope of *Leegin*. However, recall that under *United States v. General Electric Co.*, 272 U.S. 476 (1926)—a decision that was under attack on *Dr. Miles* grounds since the 1940s but has now received a new lease on life because of *Leegin*—a patent license between competitors accompanied by a resale price maintenance provision is not per se illegal.

11. Schering-Plough Corp. v. F.T.C., 402 F.3d 1056, 1076 (11th Cir. 2005).